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BMJ Open A hard pill to swallow: a qualitative study of women's experiences of adjuvant endocrine therapy for breast cancer

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ABSTRACT

Objective: To explore women's experiences of taking adjuvant endocrine therapy as a treatment for breast cancer and how their beliefs about the purpose of the medication, side effects experienced and interactions with health professionals might influence adherence.

Design: Qualitative study using semistructured, one-to-one interviews.

Setting: 2 hospitals from a single health board in Scotland.

Participants: 30 women who had been prescribed tamoxifen or aromatase inhibitors (anastrozole or letrozole) and had been taking this medication for 1–5 years.

Results: Women clearly wished to take their adjuvant endocrine therapy medication as prescribed, believing that it offered them protection against breast cancer recurrence. However, some women missed tablets and did not recognise that this could reduce the efficacy of the treatment. Women did not perceive that healthcare professionals were routinely or systematically monitoring their adherence. Side effects were common and impacted greatly on the women's quality of life but did not always cause women to stop taking their medication, or to seek advice about reducing the side effects they experienced. Few were offered the opportunity to discuss the impact of side effects or the potential options available.

Conclusions: Although most women in this study took adjuvant endocrine therapy as prescribed, many endured a range of side effects, often without seeking help. Advice, support and monitoring for adherence are not routinely offered in conventional follow-up settings. Women deserve more opportunity to discuss the pros, cons and impact of long-term adjuvant endocrine therapy. New service models are needed to support adherence, enhance quality of life and ultimately improve survival. These should ideally be community based, in order to promote self-management in the longer term.

INTRODUCTION

Adjuvant endocrine therapy has been the mainstay of breast cancer management over the past three decades.¹ Approximately 80% of breast cancers are oestrogen receptor-positive and treated with tamoxifen

Strengths and limitations of this study

- This is one of the few studies which have asked women to talk about their experiences of taking adjuvant endocrine therapy for breast cancer.
- We found that women seek to be adherent but some will miss tablets without realising the potential consequences.
- The impact of severe side effects does not necessarily affect adherence, as women's belief that taking the medication reduces their risk of recurrence outweighs these negative effects.
- Not all women who experience side effects will seek advice and support. Opportunities for monitoring adherence to and managing symptoms of adjuvant endocrine therapy are underutilised.
- Women with low adherence and those who were premenopausal were under-represented in this study.

or, for postmenopausal women, aromatase inhibitors (eg, anastrozole or letrozole).^{2 3} Tamoxifen is a selective oestrogen receptor modulator, whereas aromatase inhibitors (AIs) reduce oestrogen synthesis by blocking conversion of androgens into oestrogen. Clinical trials have shown that tamoxifen reduces the risk of disease recurrence by 11.8% and mortality by 9.2% over 5 years, and AIs are associated with even lower recurrence rates in postmenopausal women.^{4 5} Guidelines recommend 5 years of adjuvant endocrine therapy, although recent trials have shown reduced all-cause and breast cancer-specific mortality in patients using tamoxifen for 10 years compared with five.^{3 6} Extended treatment with adjuvant AIs for at least 8 years postdiagnosis has also been advocated.⁷ With recent guidelines supporting the use of tamoxifen for breast cancer prevention and successful chemoprevention with anastrozole in postmenopausal women, the issue of adherence to endocrine therapy now extends to the chemopreventive setting.^{8 9}



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Despite the survival benefit, one-third to a half of women do not complete even the recommended 5-year adjuvant course.^{10–18} Between 19% and 28% of women prescribed adjuvant endocrine therapy in the community miss at least one out of five daily doses, with a consequent associated increased risk of breast cancer recurrence and mortality.^{11 13–15 19–21} Recent work from the authors has demonstrated that women with low adherence to adjuvant endocrine therapy had an increased risk of mortality (HR=1.3, 95% CI 1.16 to 1.51, $p<0.001$), reduced quality-adjusted life years (QALYs) and increased medical costs (£5970, 95% CI £4644 to £7372).^{14 15}

Adjuvant endocrine therapy with either tamoxifen or an AI has a significant side effect profile.²² Side effects commonly reported for tamoxifen include hot flushes, weight gain and loss of libido, and less commonly thromboembolic disease or endometrial pathologies. AIs also cause hot flushes and have been associated with arthralgia, increased fractures, rash and gastrointestinal upset.^{23 24} A small qualitative study found that the side effects experienced were not always felt to be worth the perceived benefits of taking tamoxifen.²⁵ Only 3% of women attributed surviving at 3 years to adjuvant endocrine medication compared with 48% who felt that a positive attitude was more important.²⁶

The majority of studies examining adherence to adjuvant endocrine therapy have focused on measuring non-adherence in terms of number of pills taken and the impact on recurrence and mortality.²⁷ These aggregated numerical data fail to capture the diverse patterns of adherence or the complex factors which may lead to breaks in adherence, well recognised as a feature of treatment for other chronic conditions.²⁸

Although there is limited evidence to support this assumption, side effects are generally considered to be the main reason for women not continuing adjuvant endocrine therapy.^{29–31} Other factors linked to social support, lack of information and beliefs about cancer, as well as the complexities associated with taking medications for other chronic conditions are also thought to contribute to intentional non-adherence.^{32 33} Gaining an in-depth understanding of the important elements which contribute to women's beliefs about the use of this medication and examining factors which influence adherence/non-adherence will enable us to develop insights into how best to support women to continue taking long-term adjuvant endocrine therapy. This qualitative study aimed to explore women's experiences of taking adjuvant endocrine therapy; their understandings and reasons for taking or not taking medication and the factors which influenced adherence or non-adherence and the information and support they received or desired.

METHODS

Design

The study was conducted in outpatient clinics at two hospitals within the NHS Tayside health board in Scotland.

Recruitment and data collection were carried out between January 2013 and May 2013. Semistructured face-to-face interviews were conducted using a topic guide (box 1). This allowed sensitive exploration of each individual's experience of their disease and treatment, and permitted flexibility for the patient to introduce new topics, while allowing collection of data on core themes.

Participants and procedures

Participants were women who had been diagnosed with primary breast cancer and who were attending outpatient clinics for routine surgical or oncology follow-up between 1 and 5 years after diagnosis. We aimed to recruit 24–30 participants to achieve variation in our sampling to include a range of different times since diagnosis, different adjuvant endocrine therapies and where possible varying rates of self-reported adherence to treatment.

The researcher (RD) attended 14 surgical and oncology outpatient clinics in hospital 1 and hospital 2 between 24 January 2014 and 18 April 2014. The majority of these clinics were in hospital 1 as the throughput of patients was smaller in hospital 2. After routine clinic appointments, staff informed all women that a research study was being carried out into women's experiences of tamoxifen and aromatase inhibitors. Those who agreed were then introduced to RD (an experienced health services researcher but no clinical background in breast cancer) who briefly explained the study and provided written information to those women who expressed an interest in participating. As recruitment proceeded the purposive sampling criteria were increasingly applied in order to achieve maximum variation. A follow-up phone

Box 1 Topic guide

Areas to explore

1. *Perceptions and beliefs about breast cancer:*
For example, set context by discussing breast cancer diagnosis, illness perceptions and how this has varied by time.
2. *Experience and understanding of breast cancer and its treatment*
For example, explore their understanding of treatment: what it is for, what it does, how important it is for them.
3. *Beliefs, feelings and experiences about taking adjuvant endocrine therapy*
For example, general views about taking medication, specific views about this medication, any concerns or side effects.
4. *Medication routines information and support received*
For example, who have they had specific discussions about hormone medication with: for example, surgeon, BCN, GP, pharmacist, peers, what did they think about these discussions, did they have any influence on medication use.
5. *Factors which influence or might influence ongoing medication adherence or non-adherence*
For example, advice, support, information, routines, perceptions, side effects, attitudes towards cancer

call, at least 24 h after the clinic, allowed RD to provide additional information and set up an interview. Women were offered the choice of being interviewed at home or in a university location.

Data analysis

Interviews were recorded, transcribed by a professional transcription company, anonymised and checked for accuracy by RD. Analysis drew on the constant comparison method applied within the framework approach, therefore enabling us to check that data saturation had been reached.³⁴ NVivo was used to manage the data.³⁵ AH and RD developed a coding framework on the basis of the topic guide and initial analysis of transcripts. In our analysis we drew on, but were not limited by, the work of Horne and Weinman³⁶ who use illness representation theory to show that while illness beliefs play a role in adherence, patients' beliefs about the necessity of their treatment also have a direct role in medication adherence.

The first five interviews were coded by AH and RD independently. All codes and coded texts were then reviewed by AH and RD to ensure concordance was reached. MW and RD then independently coded three more transcripts until the coding frame was further refined. Coding matrices were then developed in order to identify any patterns in the data (for an example of a coding matrix see online supplementary file). Regular meetings consisting of all authors and a patient representative were held to discuss all aspects of study development, analysis and dissemination.

RESULTS

Forty-nine women who met the eligibility criteria were identified and asked to participate in one-to-one interviews. Of these, 17 women declined to take part for reasons which included not wanting to think about cancer or being too busy with caring commitments or other illnesses. Of the remaining women, two who had initially agreed to participate, and who had indicated that they did not take their medication as prescribed, were not at home at the time arranged for their interviews. Neither could be contacted to arrange a new date. Thirty women participated in semistructured one-to-one interviews (20 in women's homes and 10 in an academic setting) taking an average of 51 min per interview (range 24–102 min).

All of the participants had been prescribed tamoxifen, anastrozole or letrozole daily. Five out of 30 women described missing one or two tablets now and then, 9 women had stopped temporarily (n=6) or permanently (n=3), either following clinical advice or of their own volition. The remaining 16 women said they had taken their medication every day. Clinical and sociodemographic characteristics of the sample are shown in [table 1](#).

Table 1 Participant demographics

	Number of women (%)
Age group at interview	
<50 years	2 (7)
50–64 years	15 (50)
≥65 years	12 (40)
Age unknown	1 (3)
Type of hormone therapy	
Tamoxifen	16 (53)
Aromatase inhibitors	10 (33)
Tamoxifen and aromatase inhibitors	4 (13)
Year of treatment	
First	3 (10)
Second	4 (13)
Third	13 (43)
Fourth	7 (23)
Had stopped taking adjuvant endocrine therapy <6 months before recruitment	3 (10)
Additional treatment type	
Surgery only	6 (20)
Surgery and chemotherapy	3 (10)
Radiotherapy only	1 (3)
Surgery and radiotherapy	15 (50)
Surgery, chemotherapy and radiotherapy	5 (17)
Menopausal status at diagnosis	
Premenopausal	3 (10)
Perimenopausal	7 (23)
Postmenopausal	17 (57)
Unknown	3 (10)
Outpatient clinic recruitment source	
Surgical (hospital 2)	7 (23)
Oncology (hospital 1)	12 (40)
Surgical (hospital 1)	11 (37)
Cancer detection method	
Routine screening	12 (40)
Self-referral	18 (60)

Analysis identified eight key themes: lifeline to being cancer free; doctor knows best; it's a religion; remembering not to forget—got the routine; living with the side effects—I am still alive; no one's ever asked if I am still taking it; keeping it to themselves—everyone's different; appropriate expertise. These are presented with quotes (labelled with participant number, age range and adjuvant endocrine therapy prescribed) used to illustrate typical and/or divergent responses under the specific areas explored within the interviews. These have been grouped into three main areas: reasons for taking adjuvant endocrine therapy; experiences of taking adjuvant endocrine therapy; perceptions of and need for support. Factors which influence adherence or non-adherence have been subsumed into reasons for and experiences of taking adjuvant endocrine therapy.

Reasons for taking adjuvant endocrine therapy

When asked about their reasons for taking adjuvant endocrine therapy participants' responses were remarkably consistent.

Almost half of the women acknowledged the importance of endocrine therapy in terms of the protection it offered against cancer recurrence, recognising it as the next necessary stage of their treatment: a *Lifeline to being cancer free*. They also felt that they would not have been prescribed this medication if it was unnecessary and respected clinicians' knowledge: *Doctor knows best* (box 2).

Experiences of taking adjuvant endocrine therapy

The theme *Remembering not to forget* indicated the importance many women placed on taking adjuvant endocrine therapy as prescribed, every day. These routines generally consisted of a combination of keeping tablets somewhere they would be seen and/or taking the medication at a very specific time each day. However, having a routine was no guarantee that they would remember to take their tablets; one-fifth of the women still described forgetting occasionally. Some took their tablets late if they discovered they had forgotten, while others justified missing one or two as they felt this would make little difference to the efficacy of the medication. While some women described going to extremes to ensure they took

the medication at a particular time, others were less concerned (box 3).

Seventeen women were sure they had never missed a tablet or had detailed explanations for missing any: *It's a religion* (box 3).

Adherence was not without personal cost for some. The theme *Living with the side effects—I'm still alive* illustrates how women's beliefs about the efficacy of the medication, and their desire to continue with it as advised by health professionals, were key factors in their ongoing adherence. Women were asked if side effects of these medications had been discussed with them at the time of being prescribed and while most were aware of hot flushes and joint pains none mentioned any of the more severe side effects associated with either tamoxifen or AIs. One woman described being investigated for endometrial cancer and the majority of women prescribed an AI indicated that they had bone scans. Several described that one of the side effects of AIs could be loss of bone density or 'brittle bones'. However, they did not raise this as a major consideration in either taking or continuing with AIs.

They said that it would remove the, I can't remember the name it's something, oh dear, they did tell me what the Letrozole did and I can't remember what it removes but then if that is removed it can cause brittle bones...Which is why I've got the other tablets, they told me that I did have brittle bones and that I could if I felt I could you know break quite a lot so they prescribed the Alendronic, they didn't tell me how bad the brittle bones were, I asked the doctor and he said no I don't have that information. (Participant 22, age ≥ 65 , letrozole)

More than half found the side effects they experienced unproblematic or did not attribute their symptoms directly to adjuvant endocrine therapy.

It's painless, I don't have any side effects. It's been very easy. I consider myself really lucky. But if it's working, then I've got off easy. (Participant 13, age ≥ 65 , anastrozole)

Well, I felt more emotional, I suppose I felt more PMT-ish ...I feel I get a bit panicky, but that's, maybe, just old age, I don't know. Because you can't blame things on what you're taking. (Participant 1, age ≥ 65 , anastrozole which was changed after 3 months to tamoxifen following a bone scan)

However, the list of side effects experienced and attributed to adjuvant endocrine therapy was extensive, and more than a third described the profound impact these had on their daily lives (box 3). Several gave graphic descriptions of extreme menopausal symptoms (hot flushes and night sweats, joint pains, vaginal dryness, loss of libido, weight gain, hair loss, insomnia) as well as suicidal feelings, fatigue, allergic reactions and severe nausea. One woman's side effects led to her having investigations to rule out endometrial cancer.

Box 2 Reasons for taking adjuvant endocrine therapy

Lifeline to being cancer free

I see my tamoxifen as the lifeline to being cancer free. (Participant 27, age range 50–64, tamoxifen)

The way I see it is that this is my chance. It may be a small chance but I see it as being a chance to diminish my chances of its returning... (Participant 3, age range 50–64, letrozole)

...my body has already proved I can get breast cancer...if I've got to be on a tablet for 5 years that's going to put a protection around it, it hopefully won't happen again... (Participant 15, age range ≤ 49 , tamoxifen)

So I think I'm sure that's what they said that the surgery would cut it out, the radiotherapy would kill it externally although it did go in and the tablet, the anastrozole was to try and prevent the cancer cells reforming. (Participant 21, age range ≥ 65 , anastrozole)

Doctor knows best

I just accept what the doctor said, you know. (Participant 11, age range ≥ 65 , taking tamoxifen which was changed to anastrozole)

I suppose just because the consultant explained that that would be part of the on-going treatment and so because I'd gone through all the other bits, there was no real reason to then say I wasn't going to take letrozole. (Participant 9, age range ≥ 65 , taking letrozole)

...you get no benefit that you can see, you just have to take peoples word for it (Participant 24, age range ≥ 65 , taking letrozole)

I mean because I understand in general terms what's going on and you know if I wanted to I could go and investigate you know become a complete nerd about letrozole and all the different you know, but basically because I trust the clinical advice I'm being given. (Participant 23, age range 50–64, taking letrozole)

Box 3 Experiences of taking adjuvant endocrine therapy*Remembering not to forget—got the routine*

Got the routine, I take the dog out, come back, have all the, have a wee drop breakfast and have the rest of the pills. (Participant 22, age range 50–64, letrozole)

I was away to New York before Christmas time, well, in November. So, I had to...I was trying to, I was taking it...through the night. Because I wanted to keep it in the 24 hour clock. So, it was...I think it was four o'clock in the morning... (Participant 5, age range 50–64, tamoxifen)

If I'm day shift I am taking them at seven, if I am night shift, I'm taking them at 8 in the morning. So I am keeping them as near as possible to the twenty four hour period. (Participant 16, age range 50–64, tamoxifen)

There are quite a few times that I forget...There is sometimes that I go to the box and I have missed the day before, but I am bad for that, because if I discover that, I take them, and then I take them again, twelve hours later. (Participant 15, age range ≤49, tamoxifen)

I've sort of assumed that if you're taking a drug for five years it isn't going to really make a lot of difference you know it's not as if these poor old cells are suddenly going to start pumping the stuff out because you took it eight hours late. (Participant 23, age range 50–64, letrozole)

It's a religion

No, it's a religion, you know, it's ... I have my little blue box of pills that's counted out every day and it's in there. (Participant 13, age ≥65, anastrozole)

Never missed it, never, it's in my head you know it's something I have to do. (Participant 21, age range ≥65, anastrozole)

Well, I wouldn't forget my anastrozole, that's for sure, it's like my best friend. (Participant 11, age range ≥ 65, taking tamoxifen which was changed to anastrozole)

Living with the side effects—I'm still alive

...if I was a car engine it had just sucked all the oil out of my entire body so my knees, my shoulders ache like they've never ached before. (Participant 8, age range 50–64, tamoxifen)

...it was affecting my life quite badly; I mean you go out for a meal and you are sitting and the water is lashing off you, and you have only had a cold drink. It's really quite debilitating at times. (Participant 16, age range 50–64, tamoxifen)

Anyway immediately I noticed the hot flushes and they were terrible to start with. I was sometimes getting 7 or 8 a night and just drenched and just waking up, I couldn't sleep. (Participant 14, age range 50–64, tamoxifen)

I took it and I took it every day and I cried very day and I didn't want to live, wanted to die. (Participant 19, age range ≤49, tamoxifen)

I was just exhausted and it was just getting worse and worse and I realised that I wouldn't be able to work and I couldn't function and I couldn't see myself getting through five years of that. (Participant 30, age range 50–64, tamoxifen before stopping with support of health professionals)

I had quite a busy job...So I stopped that so you know I really could pretty much say I'm doing hardly anything and yet I'm still exhausted all the time. (Participant 18, age range 50–64, letrozole)

We're having to downsize our house so that we can accommodate the fact, because I would rather live in a smaller house costing less money, so that I have the option that if I'm still not well enough I don't have the pressure of having to go back to work. (Participant 26, age range 50–64, tamoxifen)

Unless advised to stop by health professionals, those women who described their treatment having a negative impact on their daily lives were still prepared to tolerate this in order to reduce the threat of recurrence and death.

I'm still alive but there's huge consequences that I live with every day and the knock-on effect...makes it really difficult and, you know, if you were to ask me, would I still...going back, would I still go on tamoxifen? Absolutely because I wouldn't risk cancer coming back... (Participant 26, age range 50–64, tamoxifen)

Perceptions of and need for support

Two themes were identified which indicated that women would not necessarily seek out additional support networks and that some experienced a lack of consistent monitoring of whether they were taking or coping with their medication; *Keeping it to themselves—everyone's*

different, No one's ever asked if I'm still taking it and Appropriate expertise (box 4).

Although 7 women did remember being asked about taking adjuvant endocrine therapy, 14 others were either sure they had not been asked or could not recall being asked whether they were continuing with their medication or whether they were experiencing any problems, either at follow-up clinics or by their general practitioner (GP).

However, where women did discuss the side effects they were experiencing, they were supported to explore ways of reducing their symptoms. Three women were advised to take breaks in treatment; one by the GP, who stopped her tamoxifen because of side effects which included conjunctivitis and whole-body itching. This woman's medication was restarted as soon as she attended for her routine follow-up appointment, approximately 3–5 months after the GP had told her to stop. The other two women were advised to stop at follow-up clinics (1 for 3 weeks and 1 for

Box 4 Perceptions of and need for support*Keeping it to themselves —everyone's different*

So I went and looked up, there were lots of forums and things on line, I mean and the truth is that when you read these forums, you really have to be aware that you're mainly going to read stories from people who have had problems. (*Participant 30, age range 50–64, tamoxifen before stopping with support of health professionals*)

Yes, but they do tell you people can have the same type of cancer as you and all the details be the same and yet the treatment will be different, the outcomes will be different and the experience will be different so it's not, you can't say well I'll speak to somebody else who's had the same thing I'll know exactly because you don't. (*Participant 18, age range 50–64, letrozole*)

And some of them were like the hot flushes, things like that, which people were talking about, this will happen with the tamoxifen, so I think in a way, in my head, it was kind of, well that is nothing new, I'm getting that already, I've been through, so if that is happening, I know what it is going to feel like... I know what a hot flush felt like, you know what I'm meaning? And so I just didn't I never really spoke to anybody about it. (*Participant 15, age range ≤49, tamoxifen*)

No one's ever asked if I'm still taking it

No one's ever asked if I'm still taking it. (*Participant 1, age range ≥65, anastrozole which was changed to after 3 months to tamoxifen following a bone scan*)

Nobody's asked me about it since. And the Doctor [GP] knows that I'm on it, but we never discuss it. (*Participant 2, age range ≥65, letrozole*)

No, they just said I had to speak about what I'm worrying about and I say nothing at all. (*Participant 6, age range ≥65, anastrozole*)

I can't remember whether she asked about... I mean I think they ask if I'm taking it but there's not a great deal of stress laid on it, I don't think. (*Participant 9, age range ≥65, letrozole*)

...I don't know if they ask me if I'm still taking it. I mean, I'm not sure. (*Participant 12, age range 50–64, tamoxifen*)

No, it wasn't really spoken about very much. But on the other side of it, I wasn't really wanting to talk about it. (*Participant 15, age range ≤49, tamoxifen*)

Appropriate expertise

I'm not meaning this badly, but the GPs and everything; they probably know about chemotherapy and everything, but the people at Hospital X, they are dealing with it all the time... if I say something to the Doctor I might make a comment but then have to explain it a wee bit, whereas if I am in Hospital X they know exactly what I am talking about. (*Participant 15, age range ≤49, tamoxifen*)

... I get on well with him and I find him very good but I got the impression that he [GP] didn't want to be involved in the cancer issue, he said something to the effect of 'oh that was for the hospital to deal with but how are you in regard to your other medication' and this sort of thing, it was as if that's a completely separate thing that the hospital will deal with. (*Participant 18, age range 50–64, letrozole*)

Yes, they've got a little consultation room that you can go in privately and talk to them [Pharmacist] and, you know, I think these women are very smart and they know their drugs. (*Participant 13, age range ≥65, anastrozole*)

Yes I mean I wouldn't have a problem with that, either that or the doctor you know I would chat to the doctor but yes I would go to the chemist if I had any problems with the prescriptions or the tablets. (*Participant 22, age range ≥65, letrozole*)

With the hot flushes the Pharmacist did suggest instead of taking it in the morning, to try taking it at night to see if it made any difference. But I found it made the flushes, if anything, worse at night. So I went back to taking it in the morning. (*Participant 16, age range 50–64, tamoxifen*)

The relationship isn't there... I wouldn't have thought about going to see the pharmacist to talk about my side effects with any medications, I go to the GP about that. (*Participant 20, age range not known, tamoxifen*)

No I wouldn't have thought of the pharmacist as a place to go about this I mean I would you know I would ask the pharmacist what cough medicine to buy or something like that. (*Participant 23, age range 50–64, letrozole*)

They're [pharmacists] not interested, all they're interested when you do your repeat prescriptions are your quantities. (*Participant 3, age range 50–64, letrozole*)

6 weeks) were supported by breast care nurses during this period and also when they resumed endocrine therapy. All were aged between 50 and 64 years and were at different stages of menopause. Two were prescribed tamoxifen and one, letrozole. After their temporary breaks, all three resumed taking the medication as prescribed, although they all experienced ongoing side effects.

Three women stopped adjuvant endocrine therapy completely after being advised to do so at follow-up appointments. They were told that they were at 'low risk' of recurrence and therefore could stop the medication if they felt that their side effects were too problematic. All acknowledged the clinical expertise of the health

professionals and did not describe any ongoing concerns related to stopping or feeling at greater risk of recurrence.

It was based on the doctor having said that the risk was, you know, the benefits were minimal and that if I didn't take it, it would... really, I understood that it wouldn't really matter... and I think I remember reading somewhere or hearing somewhere that they were kind of over-prescribing. Would that be right? (*Participant 28, age range ≥65, taking tamoxifen before stopping with support of health professionals*)

You've got three choices, we could change it to another one, or we could halve it, or we could take you off them altogether and when he said that he went, You could do that, you dinnae need them he says Your kind of cancer wasna bad and I went Right, I'm stopping them. (Participant 29, age range 50–64, taking tamoxifen before stopping with support of HPs)

That just made it very easy because he didn't seem particularly bothered about my not taking it...and I was thinking well maybe if we'd had this discussion six months ago, I might have just not taken it. Participant 30, age range 50–64, taking tamoxifen before stopping with support of health professionals)

Three women were intentionally non-adherent for short periods of time. They took breaks in treatment because of the side effects they were experiencing and did so *without* seeking advice.

So I actually stopped, I didn't take any for maybe just two days or something but I must have contacted the hospital or something...I can't remember if the Macmillan nurse told me to come in...but anyway they said we don't think it can be that [the side effects are due to adjuvant endocrine therapy] you'd better start them again. (Participant 17, age range 50–64, letrozole)

I never went to the doctor I just took it upon myself to stop the letrozole and I thought I'm going to start them again, so I started taking them again and I although I felt little bits of nausea it wasn't nearly as bad...so I've just kept on taking them since then and everything seems to be okay... (Participant 22, age range ≥65, letrozole)

...I was trying to keep it going till I got to the clinic but because I felt I couldn't drive my car I stopped it because it was only about ten days before my clinic appointment... But you know I mean I knew that really ten days off it wasn't going to make any difference you know in the long term, so then I got tamoxifen and I'm fine with that... (Participant 24, age range ≥65, letrozole then changed to tamoxifen)

None of the women described any discussions about or the use of concomitant medication or other approaches to ameliorate the side effects of the endocrine therapy.

Even with limited opportunities available to discuss the challenges of taking adjuvant endocrine therapy most women still continued to take this medication unless advised otherwise. Indeed many described techniques they used to ensure that they did not forget to take their tablets.

The final theme *Appropriate expertise* illustrated which women might approach to discuss questions about medication. Women said they would go to their GP to get their first prescriptions for adjuvant endocrine therapy. Most indicated that they would visit their GP with general concerns about their medication. However, decisions about changes to adjuvant endocrine therapy,

breaks in treatment or stopping treatment were always made or endorsed by hospital-based health professionals. There were indications that GPs tended to leave any medicine monitoring to their hospital colleagues.

Adjuvant endocrine therapy was generally added to a repeat prescription system after the initial GP appointment. Repeat prescriptions were either collected from pharmacies or delivered by pharmacies to the women's homes. Nearly half of the participants indicated that they either had or would ask the pharmacist about issues related to adjuvant endocrine therapy; however, there was a range of views about the degree to which pharmacists were equipped to provide appropriate support or in the case of some women it had never occurred to them to talk to the pharmacists about concerns related to taking adjuvant endocrine therapy.

So, while women acknowledged the importance of this medication and were prepared to put up with many of the side effects, they appeared to be given limited reassurance and reinforcement and were seldom offered or sought out the opportunity to discuss taking adjuvant endocrine therapy.

DISCUSSION

This study demonstrates that women go to considerable lengths and make considerable sacrifices to take their medication. Many women reported side effects of adjuvant endocrine therapy, some of which were debilitating, but these were generally accepted as a price to pay for protection against recurrent disease. None of the women in our study perceived themselves as having low adherence, and they were responsive to healthcare professionals' advice to continue, take a break or stop medication. Few described having had discussions with health professionals about side effects in the context of adherence to endocrine therapy. The approaches women took to achieve adherence differed. Some ensured that their tablets were taken within a small specified time frame, for example, by staying up until the early hours of the morning to take the medication while abroad. Other women believed they were fully adherent and had implemented routines to help them remember, but admitted they sometimes missed tablets. Given that recent studies have indicated that missing only a few tablets can have an impact on mortality, our findings suggest that there are women who would possibly benefit from closer monitoring and more discussion about side effects, alternative medication or self-management strategies to enable informed and effective adherence.¹⁵ In addition, there is *in vivo* preclinical evidence to support the advice to 'take a break' from medication which is being applied to the extended adjuvant setting. The SOLE study tests extended adjuvant letrozole, continuous for years 5–10 versus 9 months on/3 months off letrozole for years 5–10 postdiagnosis in postmenopausal ER positive breast cancer. This may provide support for a break in treatment, at least in the extending adjuvant setting, as it

compares intermittent versus continuous letrozole.³⁷ Our findings certainly indicate that some women would benefit from having time to discuss in more detail why full adherence is important in reducing their risk of breast cancer recurrence.

As found in other studies, nearly all the women interviewed in this study believed that taking the prescribed adjuvant endocrine therapy would reduce their risk of breast cancer recurrence and extend their lives.³⁸ Perceptions of benefit are important in 'decisional balance' scores whereby the advantages (pros) of taking tamoxifen are weighed against the risks (cons) of not taking it, as an indicator of ongoing adherence behaviour.³⁹ Such decisions are supported by theories based on the common-sense self-regulation model.⁴⁰ These demonstrate how patients' beliefs about the importance or 'necessity' of a medicine to control or treat an illness are combined with the level of 'concern' they have about the side effects of a drug, to influence adherence to the prescribed medication.^{41–43} Our data are consistent with the 'necessity-concerns' model. Women who were told to stop medication to alleviate side effects because they were at 'low risk' accepted this decision, perhaps because their concerns outweighed their perceptions of necessity. This group reported being diligently adherent to their medication until they were given permission to stop. Others, who stopped without advice because of the side effects they experienced, but were advised to restart endocrine therapy, appeared to be realigning their necessity beliefs in the light of the professional guidance. Studies in chronic disease have found that patients' beliefs about their medication affect intentional and non-intentional non-adherence.^{44 45} However, those who encounter conflicting medication information are known to be less adherent.⁴⁵

Our findings suggest that a patient-centred approach that takes individual circumstances and beliefs into account is likely to facilitate adherence.⁴⁶ Other studies have found that specialist breast care nurses have an important role to play in providing information and supporting adherence.⁴⁷ As evidence for the long-term consequences of cancer treatment increases, specialist nurses are likely to play a greater role in educating women about the benefits and risks of hormone therapy.⁴⁸ Interestingly, less common but serious risks of taking adjuvant endocrine therapies in the longer term, for example, bone loss, cardiovascular disease (in AIs) or endometrial cancer were not raised by any women in this study, and did not appear to be major considerations for adherence. Data from current studies such as the SOLE trial comparing continuous versus intermittent (9 months letrozole, 3 months no letrozole) from years 5 to 10 for women at risk of recurrence are likely to improve our understanding of the risks and benefits of long-term therapy.

There was little evidence of consistent, routine monitoring of medication either in the community or at follow-up clinics. Although GPs and pharmacists could play an important role in supporting adherence and

monitoring the side effects of treatment they seldom did so, and the women themselves felt that the hospital team were more knowledgeable about breast cancer and its treatment.^{49 50} However, the trend towards shorter hospital-based follow-up (with discharge at 3 years recommended by NICE) combined with the emerging evidence to support tamoxifen use for 10 years and AIs beyond 5 years, suggests that any intervention to enhance adherence will need to be situated in the community rather than the secondary care setting.⁵¹ Such models may also go some way in addressing inequalities in access and cancer outcomes in people from lower economic groups and those with low literacy who may struggle to access specialist centres and fully understand the requirements of successful treatment, including prolonged and consistent adherence to medication.^{52 53} Community pharmacy interventions have been shown to be successfully implemented in other settings.⁵⁴ This study suggests that the role of community pharmacists in supporting adjuvant endocrine therapy needs to be further developed.

There are a number of limitations to this study. This study was conducted in only two centres with the majority of participants recruited from a single centre. Women with low adherence and those who were premenopausal were under-represented in this study. However, field notes made at the time indicate that most eligible patients were approached, staff were seen to introduce the study in a neutral way and there were few women who did not attend on the day of the clinic. It would be naïve to presume that intentional non-adherence is a myth and our study may not have reached those patients who stop taking adjuvant endocrine therapy without the knowledge of their clinician or who may already have been lost to follow-up for a variety of reasons.^{52 53} Furthermore, it is likely that our sample included women who might be classed as having low adherence (taking <80% of prescribed tablets) in quantitative studies. Several women had been advised to take extended breaks or stop their medication, some who had stopped for periods of time without advice and others who frequently missed one or two tablets accounted for approximately half of our sample. They may represent the group which has been classed as having 'low adherence' in previous studies.

This work reinforces other studies that show those living with cancer are reticent in talking about adverse symptoms because they see them as insignificant in comparison to the cancer.^{55–57} Current initiatives to enhance recovery and self-management may address some of these issues, but these are not yet universally available to survivors of breast cancer.⁵⁸ Such initiatives include: holistic needs assessment using a screening tool which encompasses a comprehensive range of side effects and concerns; the cancer care review which promotes a structured discussion between the GP and person with cancer; and the extension of pharmacists' roles to include advice and support to cancer survivors (eg,

Macmillan Information Centres located in local pharmacies); all of which may serve to improve support for women taking adjuvant endocrine therapy.^{59 60} It is important that tailored initiatives are made more accessible if we are to improve and support adherence. At the very least, health professionals who encounter women on endocrine therapy should be encouraged to ask routinely about side effects, experiences and adherence issues, rather than expecting women to initiate discussions. Further qualitative studies targeting women who are known to be non-adherent would enhance the knowledge base in this area. Innovative and theory-based interventions are needed to support self-management and enhance adherence, with the ultimate aim of improving long-term survival. Finally, improved methods of measuring adherence are required for large-scale studies.

CONCLUSIONS

There is increasing evidence that adherence to adjuvant endocrine therapy for primary breast cancer impacts on survival, QALYs and the economics of cancer care.^{4 5 11 13–15 19–21} Adherence is likely to become more relevant as the evidence mounts for longer duration use of tamoxifen (from 5 to 10 years) and use of AIs beyond 5 years.^{3 6 7} In addition, the trend towards chemoprevention in women at risk of breast cancer using tamoxifen⁸ (NICE 2013) or anastrozole suggests that the issue of adherence may extend to 'healthy' populations.

There is a clear need to communicate consistently and effectively about endocrine therapy and its effects, as well as to offer ongoing support and advice in hospital and community settings. The future challenge will be to design, test and implement appropriate and effective interventions to improve adherence to adjuvant endocrine therapy in women who have survived the initial diagnosis of breast cancer, but remain at risk of recurrent disease.

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